

**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/216,506	03/22/94	SCHLEGEL	010091001

18M1/0930

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ART UNIT	PAPER NUMBER
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1813

DATE MAILED: 09/30/96

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/216,506

Applicant(s)
Schlegel et al

Examiner
Mosher

Group Art Unit
1813



☒ Responsive to communication(s) filed on Aug 7, 1996

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-3, 10-19, 21-26, 46, 47, and 50-66 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 1-3, 12-14, 16, 19, 23-25, 46, 47, 50, 52, 53, 55, and 64 is/are allowed.

☒ Claim(s) 10, 11, 15, 17, 18, 21, 22, 26, 51, 54, 56-63, 65, and 66 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Claims 56-62 and 66 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 56-58, the recitation "wherein the human papillomavirus comprises either HPV-6 or HPV-11a" is confusing, because a papillomavirus cannot comprise a papillomavirus. Is the intent to specify that the papillomavirus is either HPV-6 or HPV-11a?

In claims 59-62, the recitation "wherein said protein does not comprise virus-like particles" is confusing; since a particle is made of an assemblage of proteins, a protein compound cannot comprise a virus-like particle. Is the intent "wherein said protein is not in the form of a virus-like particle"?

Claim 66 is confusing, because it appears to be intended as a dependent claim, but fails to specify the parent claim.

Claims 10, 11, 15, 17, 18, 21, 22, 26, 51, 54, 63, 65, and 66 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to HPV types other than HPV16, for reasons of record. See M.P.E.P. §§ 706.03(n) and 706.03(z). Applicant argues that the as-filed application contains enough information to enable the production of HPV-16 proteins exhibiting appropriate conformation. Applicant argues that it would have been within the ordinary skill of the art to

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clone an HPV-L1 sequence from any infectious human papillomavirus (including HPV-16) and to express such sequence according to the teachings of the application. Applicant argues that it was well known in the art that HPV-16 DNA was frequently detected in cervical warts and premalignant cervical lesions, citing Bubb et al. Applicants state that Bubb et al exploits this fact by isolating an infectious form of HPV16 from extrachromosomal viral DNA contained within a premalignant cervical region. However, Bubb et al does not teach isolation of an infectious form of HPV16; Bubb et al teaches the sequence of an E5 open reading frame from a new isolate of HPV 16, for the purpose of analysis of "transforming genes". Bubb et al discloses a frame-shift mutation in the E5 sequence; however Bubb et al is silent upon the L1 gene and upon viral capsids of HPV 16. Applicant also argues that a keratinocyte cell line which produces intact HPV-16 virions was publicly known and available, citing Sterling et al, and that Sterling et al teaches production of a particle of about 50 nm. However, Hagensee et al (1993), published two years after Sterling et al, states on page 320 that "No clinical specimens of HPV-16 with abundant virions are available, so it is impossible to compare the in vitro-synthesised HPV-16 capsids with authentic HPV-16 virions." This indicates that those skilled in the art, even later than applicant's filing date, were either not aware of the virions of Sterling et al, or did not consider them as

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representative of authentic HPV-16 virions. In addition, considering that Sterling et al observed particles only in the nuclei of differentiated keratinocytes obtained after a complicated procedure involving grafting of human cells into prepared tissue sites in nude mice, the cell line itself is not seen as "a continuous source of HPV-16 virions" readily available to the practitioner. Considering that success in obtaining HPV-16 products would have required experimentation beyond that required for other HPV types; considering that the instant specification gives little guidance as to the particular types of experimentation required to obtain the claimed HPV-16 products; considering that those in the art have not been shown to be familiar with sources of the HPV-16 virions required as starting material by the directions present in the specification, or familiar with monoclonal antibodies recognizing conformational epitopes of HPV 16 L1; considering the overall state of the art and the lack of a working example, it is maintained that undue experimentation would have been required to enable the HPV 16 species claimed.

Claims 1-3, 12-14, 16, 19, 23-25, 46, 47, 50, 52, 53, 55, and 64 are allowable.

Claims 56-62 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. 112.

The publications cited by applicant in the response filed

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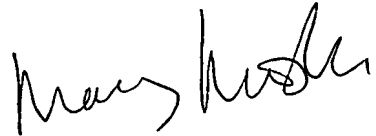
August 7, 1996, have not been considered even to the extent relied upon in applicant's arguments, because no copies were provided with the response.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph. D., whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday-Thursday from 6:30 AM-4:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christine Nucker, can be reached on (703) 308-4028.

The fax phone number for art unit 1813 is (703) 305-7939. Certain papers related to this application may be submitted by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (October 19, 1988) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800

September 26, 1996